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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/196,447 11/19/98 TRIPP

C 2618-13-3-1

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EXAMINER

SWARTZ, R	
ART UNIT	PAPER NUMBER

1645

DATE MAILED:

06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/196,447

Applicant(s)

Frank et al

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18December1998.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-54 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 20) ☐ Other:

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DETAILED ACTION

1. Applicants' Preliminary Amendment, received 18 December 1998, paper#2, is acknowledged. Claims 1-42 have been canceled without prejudice or disclaimer and new claims 43-54 have been added.
2. Currently, claims 43-54 are pending and under consideration.

Drawings

3. This application has been filed with drawings which are acceptable for examination purposes only. The drawings are objected to for the reasons set forth on the attached form PTO-948.

Specification

4. The disclosure is objected to because of the following informalities:
 - a) page 1, line 3-8 contain blanks, i.e, U.S. Patent No. _____, issued on _____; the status of the listed priority documents should be included,
 - b) throughout the specification are listed sequences which are not labeled with a corresponding SEQ ID NO.;

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 43-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibody which binds to a filariid p22U protein, does not reasonably provide enablement for an antibody which selectively binds, i.e., does not cross-react with other proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to an isolated antibody which "selectively binds" to a filariid p22U protein.

The specification teaches the production of antibodies by immunizing dogs with larval stage *D. immitis*, then testing the reactivity of isolated *D. immitis* protein with either immune or pre-immune serum. The specification is silent concerning the reactivity/crossreactivity of the antibodies in the immune serum, i.e., there are no data indicating that the antibodies are "selective".

8. Claims 46, 52, 53 and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for serum from immune dogs reducing the growth of *D.*

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immitis in mice receiving said immune serum, does not reasonably provide enablement for a composition or method of protecting the recipient animal from infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

The claims are drawn to a composition which "protects an animal from infection by a filariid", and a method of use of the composition to protect said animal from infection by a filariid.

The specification teaches the production of antibodies by immunizing dogs with larval stage *D. immitis*, and transferring said serum to mice which are infected with *D. immitis* larvae. The serum does not protect the mice from infection, but merely reduces the growth rate of the larvae.

9. Claims 43-48 and 50-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies which bind to *D. immitis* p22U protein, does not reasonably provide enablement for antibodies which bind to any and all other filariid p22U proteins nor methods for cross protection against any and all other filariids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

The claims are drawn to an isolated antibody which "selectively binds" to a filariid p22U protein.

The specification teaches the production of antibodies by immunizing dogs with larval stage *D. immitis*, then testing the reactivity of isolated *D. immitis* protein with either immune or

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pre-immune serum. The specification is silent concerning the binding of any other proteins to the immune serum and is silent concerning passive transfer experiments using any other filariid other than *D. immitis*.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 43-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Tulloch et al (*Amer. J. Vet. Res.* 31(3):4370448, 1970).

The claim are drawn to an isolated antibody that selectively binds to a filariid p22U protein.

The specification teaches the production of antibodies by immunizing dogs with larval stage *D. immitis*, then collection of whole sera from said dogs.

Tulloch et al teach the production of antibodies by immunizing dogs with larval stage *D. immitis*, then collection of whole sera from said dogs (section **Materials and Methods**, pages 438-439; section *Serologic Test Results*, pages 442-443; Figures 5 and 6).

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Because the immunizing composition in both the claimed invention and the cited reference is larval stage *D. immitis*, and the animals are dogs, the whole sera of Tulloch et al would inherently comprise the antibodies of the claimed invention.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER

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June 26, 2001